

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

KARL F. POPP

Serial No. 10/044,275

Filed: January 10, 2002

For: METRONIDAZOLE PLEDGET

Art Unit: 1615

Examiner: Humera N. Sheikh

Assistant Commissioner for Patents
Washington, DC 20231

Declaration by Inventor of Prior Invention Under 37 C.F.R. 1.131

I, Karl F. Popp, declare as follows:

1. This declaration is to establish completion of the invention in this application in the United States, at a date prior to January 19, 2001, the filing date of the U.S. Patent No. 6,495,158 to *Buseman, et al.* (the "Cited Reference") cited by the Examiner in the first office action (paper number 4) as a basis for rejecting claims 2-11, 14, 22-28 and 30-37 under 35 U.S.C. §103(a).

2. The person making this declaration is the inventor.

3. The following statements are submitted to establish a date of completion for the invention disclosed in the instant application at a date prior to January 19, 2001:

- a. The inventor conceived the idea of using a pledget for the delivery of a metronidazole solution including a major solvent component sometime during 1995 in the United States.
- b. As reflected in confidential corporate records of the assignee of record, the present invention, as disclosed and claimed in the present application, was

discussed at various product development meetings in which the inventor participated. The earliest of such meetings occurring at least as early as December 10, 1996 in the United States. Attached hereto as Exhibit "A" is a page from said confidential corporate records evidencing this fact.

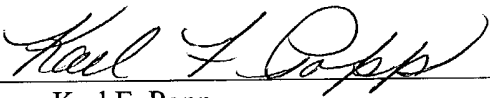
- c. As reflected in confidential corporate records of the assignee of record, the invention as disclosed and claimed in the present application was actually reduced to practice at least as early as August 14, 1997 in the United States. Attached hereto as Exhibit "B" is a page from said confidential corporate records evidencing this fact.
- d. The inventor and assignee of record have diligently and continuously pursued development and refinement of the present invention in the United States from the 1995 date of conception through and beyond March 28, 2001, the date of filing of U.S. Provisional Patent Application Serial No. 60/279,382 to which priority has been claimed in the present non-provisional application.

4. From the above documentation and statements, it can be seen that the invention in this application, as disclosed and claimed in the present application, was conceived in the United States at least as early as December 10, 1996, and actually reduced to practice in the United States as early as August 14, 1997, both of which dates are earlier than the effective date of the Cited Reference.

5. This declaration is submitted with the Applicant's response to the first office action, and is for the purpose of overcoming the Examiner's rejection under 35 U.S.C. §103(a).

I declare, under penalty of the perjury laws of the United States, that all statements made herein of my own knowledge are true and that all statements made based on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Respectfully submitted,

By: 
Karl F. Popp

Date Signed 3 November 2003